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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: OKAJIMA1

In re Application of:)	Conf. No.: 2332
)	
Kenji OKAJIMA et al)	Art Unit:
)	
Appln. No.: 10/540,852)	Examiner:
)	
Filed: June 27, 2005)	Washington, D.C.
)	
For: MEDICAMENT FOR IMPROVING)	January 13, 2006
PROGNOSTIC SURVIVAL IN)	
THERAPY OF MALIGNANT TUMOR))	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building, Mail Stop Amendments
401 Dulany Street
Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114; or

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below):

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein either was

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this IDS.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant states as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein either was

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this IDS.

Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

☒ 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:

☐ A. Document(s) _____ is/are deemed substantially cumulative to document(s) _____, and, in accordance with 37 CFR §1.98(c), a copy of each of the former document(s) is not enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made of record in accordance with 37 CFR §1.98(d). Per 37 CFR

§1.98(d), copies of these documents need not be filed in this application.

[X] 3. Document(s) AC, AE, AG, AN, AP, AX, and BH are not in the English language. In accordance with 37 CFR

§1.98(a)(3), Applicant states:

[X] An English translation of each document AN, AP, AX, and BH (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.

[X] For documents AC, AE, and AG, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.

[] A concise explanation of the relevance of document(s) _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of document(s) _____ is set forth as follows:

[] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

[] A concise explanation of the relevance of document(s) _____ can be found on the attached sheet.

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

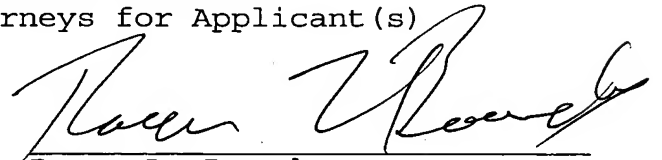
[] 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By:


Roger L. Browdy
Registration No. 25,618

RLB:rd
624 Ninth Street, N.W., Suite 300
Washington, D.C. 20001-5303
Telephone: (202)628-5197
Facsimile: (202)737-3528
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Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet	1	of	3
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Complete if Known

Application Number	10/540,852
Filing Date	June 27, 2005
First Named Inventor	Kenji OKAJIMA
Group Art Unit	
Examiner Name	
Attorney Docket Number	OKAJIMA

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-4,775,624	10-04-1988	Bang et al	
	AB	US-5,147,638	09-15-1992	Esmon et al	
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T-2
	AH	AOKI et al, "A comparative double-blind randomized trial of activated protein C and unfractionated heparin in the treatment of disseminated intravascular coagulation", <u>Int J Hematol</u> 75(5):540-547 (2002)	
	AI	BAJZAR et al, "The profibrinolytic effect of activated protein C in clots formed from plasma is TAFI-dependent", <u>Blood</u> 88(6):2093-2100 (1996)	
	AJ	BERNARD et al, "Efficacy and safety of recombinant human activated protein C for severe sepsis", <u>N Engl J Med</u> 344(10):699-709 (2001)	

Examiner
Signature

Date
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.



Institute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/540,852
		Filing Date	June 27, 2005
		First Named Inventor	Kenji OKAJIMA
		Group Art Unit	
		Examiner Name	
Sheet 2	of 3	Attorney Docket Number	OKAJIMA1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	AK	COMP et al, "Determination of functional levels of protein C, an antithrombotic protein, using thrombin-thrombomodulin complex", <u>Blood</u> 63(1):15-21 (1984)	
	AL	GLASSMAN et al, "Thrombosis and coagulation abnormalities associated with cancer", <u>Ann Clin Lab Sci</u> 24(1):1-5 (1994)	
	AM	HALKIN et al, "Reduction of mortality in general medical in-patients by low-dose heparin prophylaxis", <u>Ann InternMed</u> 96(5):561-565 (1982)	
	AN	IKEDA Y, "Atarashii Kokessen 'yaku Kakuron' Kogyokoyaku (2) Kasseika Protein C", <u>Iyaku Journal</u> 35(4):1061-1066 (1999)	
	AO	JOYCE et al, "Disseminated Intravascular Coagulation in Severe Sepsis Patients Treated with Recombinant Human Activated Protein C, a Retrospective Subgroup Analysis from the PROWESS Trial", <u>Blood</u> 98(11):445a, 43 rd Annual Meeting Program Abstracts, #1866 (2001)	
	AP	KATSUURA Y, "Kokessen 'yaku no Genjo to Shin' yaku Kaihatsu Kasseika Protein C no Kokessen Sayo", <u>Folia Pharmacologica Japonica</u> 116(5):290-297 (2000)	
	AQ	KINGSTON et al, "Peri-operative heparin: a possible adjuvant to surgery in colo-rectal cancer", <u>Int J Colorect Dis</u> 8(2):111-115 (1993)	
	AR	KISIEL et al, "Anticoagulant properties of bovine plasma protein C following activation by thrombin", <u>Biochemistry</u> 16(26):5824-5831 (1977)	
	AS	KISIEL W, "Human plasma protein C: isolation, characterization, and mechanism of activation by alpha-thrombin", <u>J Clin Invest</u> 64(3):761-769 (1979)	
	AT	KOHANNA et al, "Effect of perioperative low-dose heparin administration on the course of colon cancer", <u>Surgery</u> 93(3):433-438 (1983)	
	AU	LACAPRA et al, "The use of thrombus precursor protein, D-dimer, prothrombin fragment 1.2, and thrombin antithrombin in the exclusion of proximal deep vein thrombosis and pulmonary embolism", <u>Blood Coagul Fibrinolysis</u> 11(4):371-377 (2000)	
	AV	LEBEAU et al, "Subcutaneous heparin treatment increases survival in small cell lung cancer", <u>Cancer</u> 74(1):38-45 (1994)	

Examiner Signature	Date Considered
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3

of 3

Complete if Known

Application Number	10/540,852
Filing Date	June 27, 2005
First Named Inventor	Kenji OKAJIMA
Group Art Unit	
Examiner Name	
Attorney Docket Number	OKAJIMA1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	AW	LORETO et al, "Coagulation and cancer: implications for diagnosis and management", <u>Patho Oncol Res</u> 6(4):301-312 (2000)	
	AX	MITATE et al, "Kessensho no Rinsho-Ekigaku to Byotai DIC-Byotai no Tayosei", <u>Medicina</u> 37(5):735-737 (2000)	
	AY	MURAKAMI et al, "Activated protein C prevents LPS-induced pulmonary vascular injury by inhibiting cytokine production", <u>Am J Physiol</u> 272(2 Pt 1):L197-L202 (1997)	
	AZ	REZAI A, "Vitronectin functions as a cofactor for rapid inhibition of activated protein C by plasminogen activator inhibitor-1. Implications for the mechanism of profibrinolytic action of activated protein C", <u>J Biol Chem</u> 276(19):15567-15570 (2001)	
	BA	SAKATA et al, "Activated protein C stimulates the fibrinolytic activity of cultured endothelial cells and decreases antiactivator activity", <u>Proc Natl Acad Sci USA</u> 82(4):1121-1125 (1985)	
	BB	SCATES S, "Diagnosis and treatment of cancer-related thrombosis", <u>Semin Thromb Hemost</u> 18(4):373-379 (1992)	
	BC	SUTHERLAND et al, "Thromboembolic complications of cancer: epidemiology, pathogenesis, diagnosis, and treatment", <u>Am J Hematol</u> 72(1):43-52 (2003)	
	BD	SUZUKI et al, "Inactivation of human coagulation factor V by activated protein C", <u>J Biol Chem</u> 258(3):1914-1920 (1983)	
	BE	TAYLOR et al, "Protein C prevents the coagulopathic and lethal effects of Escherichia coli infusion in the baboon", <u>J Clin Invest</u> 79(3):918-925 (1987)	
	BF	ZACHARSKI L, "Basis for selection of anticoagulant drugs for therapeutic trials in human malignancy", <u>Haemostasis</u> 16(3-4):300-320 (1986)	
	BG	ZACHARSKI L, "Heparin and cancer", <u>Thromb Haemost</u> 80(1):10-23 (1998)	
	BH	The Welfare Ministry, Research team for specified diseases, coagulopathy, Report in 1987 p.37-41 (1988)	

Examiner
SignatureDate
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